Information to the patient with an implantable device

Madam, Sir,

You have been implanted with a Silicone Pyelostent® or a Silicone Stenostent® double loop ureteral stents for treatment purpose. Please read carefully the below information for optimal follow-up.

How to manage follow-up of my implanted device?

- It is recommended to maintain a good fluid intake after surgery and, if needed, to follow specific diet as advised by your physician.
- You have been supplied an implant card completed by your physician. This card mentions your name, your implantation
 date, your healthcare institution/provider and its address together with information on the implanted device and the
 manufacturing company.
- This card must be kept with you for the whole implantation duration to inform any other healthcare professionals of your implanted device.
- This stent is purported to stay in your body for a certain while, from a few days to several months (maximum 12 months), depending on your disease and as prescribed by your physician. You are advised to not forget your removal date.
- You are advised to consult your physician for regular monitoring of your stent as planned after the procedure to evaluate
 the treatment efficacy and check for any complication. The monitoring schedule greatly depends on the intended
 implantation duration and if you have a history of urinary stone.

What are "Silicone Pyelostent® & Stenostent®" double loop ureteral stents?

- A double loop ureteral stent is a flexible hollow tube equipped with a loop at each tip.
 - Silicone Pyelostent® double loop ureteral stent has an enlarged diameter along 80 mm of the renal end of the straight section. It is implanted in your ureter to allow urine drainage between the kidney and the bladder during management of localized stenosis of ureteropelvic junction.
 - Silicone Stenostent® double loop ureteral stent has an enlarged diameter along the entire length of the straight section. It is implanted in your ureter to allow urine drainage between the kidney and the bladder during management of ureteral stenosis.
- "Silicone Pyelostent® & Stenostent®" are double loop ureteral stents made of Mix blend of Silicone (>84% from which Yellow pigment (>0.1%) and Barium Sulfate (>0.05%)), Bismuth oxide (>14%) and Black ink (<0.1%).

Which precautions should I take?

- Inform your physician in case of any allergy known to one of the above components
- This device may act as a foreign body and be associated with inconveniences: some of them are mild and temporary
 like limited and transient pain, discomfort when urinating or during physical activities, frequent or urgent need to urinate,
 or possible sexual dysfunction
- In some cases, complications like infection, stent migration, obstruction or breakage of the stent, may need urgent care: In case of any abnormal feeling like sustained pain, cloudy urine, bladder irritation, blood in the urine or any difficulty with urination, you are advised to immediately inform your physician.
- The practice of violent sports or strenuous physical activities is not recommended. The practice of sport should be evaluated by your physician.

<u>I have an implanted "Silicone Pyelostent®" or "Silicone Stenostent®" double loop ureteral stents. Can I safely pass medical imaging exams or airport security?</u>

- In case of any medical, surgical or exploratory procedure, you are advised to inform the attending physician of your
 implanted device and show him your implant card.
- There is no contraindication to perform a MRI scan and no interference with any external equipment.

Be aware that:

- This device is for single use and should not be re-used.
- After removal, this device is dirty and should be discarded according to the hospital policy.